

K221637 Surgical Gown (Sterile)Sep 29, 2022
115 days to decisionK221637 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k221637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 6, 2022
Decision date	Sep 29, 2022
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Surgical Gown (Non-sterile)

APPLICANT

Company	Allmed Medical (Hubei) Protective Products Co., Ltd.
Location	Zhijiang, CN
Contact	Vince Tian
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221637/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026